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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/706,562	02/28/85	MONTAGNIER L.	220.4133P

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EXAMINER	
MOSKOWITZ, M	
ART UNIT	PAPER NUMBER
124	6

DATE MAILED: 04/01/86

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~_____ days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☑ Notice of Insufficient Fee, PTO-1094

Part II SUMMARY OF ACTION

1. ☑ Claims 1-14 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 1-14 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☑ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☑ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☑ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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PLEASE REFER TO THE FOLLOWING:	GROUP ART UNIT 124
APPLICANT(S) MONTAGNIER	
SERIAL NUMBER 706,562	FILING DATE 2/28/85
TITLE	

NOTICE OF INSUFFICIENT FEE AND/OR INFORMAL DRAWINGS

Correction of the informality checked below is required.
APPLICANT IS GIVEN TWO (2) MONTHS WITHIN WHICH TO SUBMIT THE FORMAL DRAWINGS AND / OR FEE to avoid abandonment of the application.

1. ☐ The filing fee of $_____ submitted in this application is insufficient.

   A balance of $_____ is due for additional claims or embodiments of a multiple dependent claim.

2. ☒ The photoprints submitted in lieu of formal drawings have been accepted for filing only (Rule 85).

   Formal drawings complying with Rule 84 together with the comparison fee of $10 (or authorization to use a deposit account) are required.

   The Drafting Division of the Patent and Trademark Office does not have the facilities for preparing new drawings at the present time.

   To ensure prompt processing and forwarding of the formal drawings to the examiner, each sheet should include the Serial Number and Group Art Unit in the upper right margin.

_____
Head, Application Branch

FOR USE IN TRANSMITTING FORMAL DRAWINGS AND / OR FEE

Check the appropriate box below.

☐ Check for $_____ enclosed.

☐ Charge $_____ to my Deposit Account No._____.
Two copies of this letter are enclosed.

_____
Authorized Signature

The above is to cover the

☐ comparison fee.

☐ balance of filing fee due.

Please transmit the formal drawings and / or fee together with a copy of this form.
BE SURE TO ADDRESS THE GROUP ART UNIT SHOWN ABOVE.

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 120, Art Unit 124.

2. Applicants are encouraged to file an information disclosure statement including (1) a form PTO-1449, "Information Disclosure Citation" listing patents, publications and other information material to the instant application (2) a concise explanation of the relevance of each listed item and (3) a copy of each listed item as a means of complying with the duty of disclosure set forth in 37 CFR 1.56. See 37 CFR 1.97 through 1.99 and MPEP 609.

3. The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157; In re Hawkins, 486 F.2d 579, 179 USPQ 163; In re Hawkins, 486 F.2d 577, 179 USPQ 167.

4. The attempt to incorporate subject matter into this application by reference to publications, pending US applications and foreign applications recited on lines 27-30 of page 2 and lines 1-11 on page 3 of the specification is improper because essential material may not be incorporated by reference to a non-patent publication, pending US application or foreign application. See MPEP 608.01(p)B.

5. The disclosure is objected to because of the following informalities:

The serial number and filing date have been omitted on lines 9 and 10 of page 3 of the specification.

Appropriate correction of the disclosure is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure.

The specification does not disclose a "means for detecting" comprising an extract of a T lymphocyte of a patient which does not have AIDS or LAS as claimed in

claim 13. Note page 19 of the specification teaches only a control antigen comprising a T-lymphocyte extract.

7. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

8. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are vague and indefinite in failing to adequately define the nature of viruses referred to by the recitations "the T leukemia viruses HTLV, including the virus HTLV-I," "the HTLV viruses" and "T leukemia HTLV viruses". It is not clear what viruses are intended to be encompasses by said terminology. It is further not clear whether applicants are asserting that LAV is immunologically distinct from HTLV-III or that the p25 of LAV is immunological distinct from the p24 of HTLV-III. Clarification of the metes and bounds of said recitations and use of consistent terminology is suggested. The term "the immunological reaction" in claim 6 lacks proper antecedent basis in claim 1. Use of the terminology "the immunological formation of a complex" is suggested. Claim 7 is unclear and confusing in the recitation of "the patient's infection with AIDS or LAS" as a patient can not be infected with a syndrome.

Recitation of "infection with lymphadenopathy virus (LAV)" is suggested. Claims 2-4, 8, 10, 11 and 14 are indefinite and unclear in failing to recite the source and nature of "a p25 protein". Note a 25 kd protein could be derived from a myriad of virally unrelated sources. Recitation of the LAV source of said protein is suggested. The term "the p19 protein" in claims 3, 5 and 11 lacks proper antecedent basis. Claims 3, 5 and 11 are vague and indefinite in failing to adequately define the nature of and criteria for immunological relation in the recitation of a "p19 protein which is immunologically related to" the HTLV p19 protein. Note a non-viral protein may have an epitopic determinant present on HTLV p19 but be otherwise unrelated. Reletion of this phrase is suggested. The term "the p25 protein" in claim 14 lacks antecedent basis in claim 9. Dependency from claim 10 is suggested. Claim 13 is totally unclear in the recitation of an extract of a single T-lymphocyte. It is not clear how a single lymphocyte extract provides a reagent sufficient to perform an assay. Kit claims 9-14 are unclear and incomplete in failing to adequately define the relationship between the elements of the kit and the assay for which the kit is designed. Note it is not clear in claims 9-14 how the p18 and p25 proteins relate to the assay nor

what is the nature of "a complex". Claims 9-14 would further be clearer if amended to recite that the elements of the kit are present in amounts sufficient to perform the assay. Claims 1-14 would be clearer if claims 1, 7 and 9 were amended to change "LAV antibodies" to recite--antibodies which bind to LAV-- as LAV can not itself produce antibodies.

9. Claim 13 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 13, drawn to a T-lymphocyte extract means, is dependent from claim 12, drawn to a human anti-immunoglobulin or protein A means. A T-lymphocyte extract means is an alternative means to the means recited in claim 12 and not a further limitation of the means recited in claim 12 as it differs in source and nature. Note it would appear from page 19 of the specification that the T lymphocyte extract is meant to be used as a control antigen and not as a detection means. See the rejection of paragraph 6 above. Amendment of claim 13 to depend from claim 9 and to recite a control antigen is suggested.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

11. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

14. Claims 1-8 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Montagnier et al (Cold Spring Harbor, Sept. 15, 1983) or Barre-Sinoussi et al (Science, May 1983).

Claims 1-8 are drawn to immunoassays to detect the presence of antibodies to proteins of the lymphadenopathy virus (LAV) comprising contacting a biological sample of a patient with "a composition containing a p18 protein of a lysate of the lymphadenopathy retrovirus (LAV)." Montagnier et al (pages 375-376) teach an enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against LAV comprising contacting patient sera with lysates of LAV. Barre-Sinoussi et al (figure 3(A)) teach a radio-immune precipitation assay (RIPA) comprising contacting patient sera with LAV-infected cell extracts. Although not explicitly recited in these references, the lysate taught by Montagnier et al and the extract taught by Barre-Sinoussi et al necessarily contain p18 and p25 proteins as these are gag proteins produced by LAV. See, for example, figure 4 of Montagnier et al (Science, July 6, 1984); "Viral Proteins-gag" section on page 13 of Wain-Hobson et al (Cell, January 1985) and figure 1 of Montagnier et al (Virology 1985) which teach that p18 and p25 are normal LAV proteins. The methods of claims 1-8 are therefore anticipated by the explicit and inherent teachings of applicants' own earlier publications.

15. Claims 1-8 are rejected under 35 U.S.C. 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over US Patent No. 4,520,113 to Gallo et al.

Gallo et al teach immunoassays for the detection of antibodies against HTLV-III comprising contacting patient sera with lysates or fractions of HTLV-III. Although not explicitly stated in Gallo et al, the methods and compositions containing LAV p18 and/or LAV p25 are inherent in Gallo et al in view of the accumulating evidence that LAV and HTLV-III are immunologically highly related, if not identical viruses. Applicants' atttention is directed to Norman et al (Science, Nov. 1985) for teachings on this point. The immunoassays of Gallo '113, therefore, anticipate the methods of claims 1-8.

16. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59-85 of copending application serial no. 06/558,109 and claims 22-33 of copending application serial no. 06/785,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods using retroviral lysates or extracts claimed in applications serial no. 06/558,109 and 06/785,638 are species of the genus claimed in the instant application as the p18 and p25 proteins necessarily are present in LAV lysates and extracts.

17. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not

patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

18. Claims 9-14 are rejected under 35 U.S.C. 103 as being unpatentable over Barre-Sinoussi et al (Science, May 1983) and Montagnier et al (Cold Spring Harbor, September 15, 1983) and US Patent No. 4,520,113 to Gallo et al.

Claims 9-14 are drawn to kits for the practice of the assays of claims 1-9. The reagents of the claimed kits are taught by Barre-Sinoussi et al, Montagnier et al and Gallo et al '113 as discussed above. Given the teachings of the immunoassay methods and reagents for the practice of said methods in Barre-Sinoussi et al, Montagnier et al and Gallo et al '113 it would have been obvious for a person having ordinary skill in the art to assemble said reagents into a kit for the expected benefits of organized ease of repeatedly practicing said assays on multiple biological samples from patients with LAS or AIDS.

14. Applicants' attention is directed the fact that no certified copies and/or translations of the foreign applications from which applicants are claiming benefit of priority under 35 USC 119 have been made of record in the instant application.

Any inquiry concerning this communication should be directed to examiner Margret Moskowitz at telephone number 703-557-3920.

Margaret Moskowitz

MARGARET M. MOSKOWITZ
EXAMINER
ART UNIT 127

Moskowitz:tgh

A/C 703

557-3920

3-24-86:retyped:3-26-86